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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/230,048	03/12/1999	BERNHARD FLECKENSTEIN	058315/0129	4939

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EXAMINER

KAUSHAL, SUMESH

ART UNIT	PAPER NUMBER
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1636

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DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/230,048

Applicant(s)

FLECKENSTEIN ET AL.

Examiner

Sumesh Kaushal Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-53 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36-45, 47-49, 52 and 53 is/are allowed.
- 6) ☒ Claim(s) 46, 50 and 51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Applicant's response filed on 03/26/03 has been acknowledged.

Claims 13-15, 17 and 29-33 are canceled..

Claims 40-42, 44, 46, 50-51 are amended.

Claims 36-53 are pending and are examined in this office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The references cited herein are of record in a prior Office action.

► *Applicants are advised to follow Amendment Practice under revised 37 CFR §1.121 (<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>). Each amendment document that includes a change to an existing claim, or submission of a new claim, **must include a complete listing of all claims** in the application. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.*

Claim Rejections - 35 USC § 102

Claims 46 and 51 stand rejected under 35 U.S.C. 102(e) as being anticipated by Ganem et al (US 5,861,240, 1999, filed 02/28/1996, *ref of record*) for the same reasons of record as set forth in the office action mailed on 11/27/02.

The scope of invention as claimed encompasses an isolated nucleic acid molecule which hybridizes the nucleic acid molecule of SEQ ID NO:1 and a fragment of polypeptide encoded by amino acid of SEQ ID NO:2.

The cited art clearly teaches the identification of expressed viral genes in infected and uninfected cells (col. 8. line 64-67). The cited art teaches a cell line (BCBL-1, ATCC CRL 11982) encoding HHV-8 genomic DNA that is capable of producing HHV-8 viral particles

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(col.9, line 35-46). The cited art further teaches the detection of HHV-8 polypeptides in a biological sample using immunochemical assays (col.5, line 3-16, line 31-38).

Response to arguments

The applicant argues that the cited art does not teach a recombinant v-IL-6 product. The applicant further argues that fig-1 does not include the complete viral genome and the V-IL-6 protein gene is one that is missing in the figure. The applicant further argues that cited art does not disclosed any homology between V-IL-6 and mammalian IL-6. The applicant argues that the claim as amended now recite a recombinant product that is not present in the cited art conditions even inherently (response, page 4-5).

However, this is not found persuasive because the scope of invention as claimed encompasses an isolated nucleic acid molecule which hybridizes the nucleic acid molecule of SEQ ID NO:1 and a fragment of polypeptide encoded by amino acid of SEQ ID NO:2. If the composition is physically the same it must have the same properties. In instant case the cited art clearly anticipate the invention as claimed because the composition and functions as claimed are presumed inherent in this context. "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990) see MPEP § 2112.02.

In instant case the cited art clearly teaches the identification of expressed viral genes in infected and uninfected cells (col. 8. line 64-67). The cited art teaches a cell line (BCBL-1, ATCC CRL 11982) encoding HHV-8 genomic DNA that is capable of producing HHV-8 viral particles (col.9, line 35-46). The cited art further teaches the detection of HHV-8 polypeptides in a biological sample using immunochemical assays (col.5, line 3-16, line 31-38). Therefore, the HHV-8 nucleic acid sequences as taught by Ganem would certainly hybridize with the nucleic acid of SEQ ID NO:1 as claimed and would inherently encodes v-IL-6 like activity. In addition, the cited art clearly anticipated the invention as claimed in claim 51, since the instant claim only requires a fragment of a polypeptide recombinantly obtained from DNA of HHV-8. Given the broadest reasonable interpretation the invention as claimed encompasses a cell culture media obtained from the cells encoding HHV-8 genome to produce viral particles and related

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polypeptides. Thus the invention as claimed has been clearly anticipated by the cited art of record.

Claim 50 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 50 recites the limitation "the isolated nucleic acid molecule of claim 45" in line 1. There is insufficient antecedent basis for this limitation in the claim, since claim 45 is drawn to an isolated polypeptide having amino acid sequence of SEQ ID NO:2.

In addition the instant claim recites limitation "the isolated nucleic acid molecule produced by recombination". It is unclear how the recombination was achieved in the cell culture media and what were the nucleic acid segments those were recombined. Recombination is considered as a natural formation in offspring of genetic combinations not present in parents, by the processes of crossing over or independent assortment.¹

Conclusion

Claims 36-45, 47-49 and 52-53 are allowed

Claims 46, 50 and 51 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838. The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yucel Irem Ph.D. can be reached on 703-305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-8724 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
Patent examiner



JEFFREY FREDMAN
PRIMARY EXAMINER